510(k) Summary

SEP - 8 2004

K041923

Submitted by:
Kensey Nash Corporation
55 East Uwchlan Avenue
Exton, PA 19341 USA

Contact:
Deborah A. Racioppi
Telephone: 610-594-4389
Facsimile: 610-524-0265

Date: July 9, 2004

Device:

Trade name:	BioBlanket™
Common/Usual Name:	Surgical Mesh, Tissue Repair Biomaterial
Classification Name:	Surgical Mesh (79FTM, 878.3300)
Regulatory Class:	Class II

Predicate Device:
The device is similar to predicate collagen-based surgical mesh devices previously cleared for commercial distribution. The relevant predicate device is Organogenesis' FortaFlex™, which was cleared by FDA under 510(k) number K011025.

Statement of Substantial Equivalence:
BioBlanket™ is substantially equivalent to the predicate device, having similar intended use, technological characteristics, performance and material.

Intended Use:
BioBlanket™ Surgical Mesh is indicated for use in general surgical procedures for reinforcement of soft tissue where weakness exists and for the repair of ruptured or damaged soft tissues. The device is supplied sterile and is intended for one time use.

Device Description:
BioBlanket™ is comprised of a single layer porous, cross-linked collagen patch that is supplied sterile in the form of a pad. This pad will be available in 2 different sizes, 5 cm x 5 cm and 5 cm x 10 cm, both with a 1.0 mm ± 0.25 mm thickness.

Performance Data:
BioBlanket™ was subjected to biocompatibility, integrity and performance tests. The device passed the requirements of all tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2004

Ms. Deborah A. Racioppi
Regulatory Affairs Specialist
Kensey Nash Corporation
55 East Uwchlan Avenue
Exton, Pennsylvania 19341

Re: K041923
Trade/Device Name: BioBlanket™ Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: July 15, 2004
Received: July 16, 2004

Dear Ms. Racioppi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section IV – Statement of Intended Use

Indications For Use Statement

510(k) Number (if known): K 04 1923

Device Name: BioBlanket™ Surgical Mesh

Indications for Use:

BioBlanket™ Surgical Mesh is indicated for use in general surgical procedures for reinforcement of soft tissue where weakness exists and for the repair of ruptured or damaged soft tissues. The device is intended for one time use.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-the-Counter Use____

(per 21 CFR 801.109)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K04/1923